

## AMENDMENT &amp; RESPONSE UNDER 37 C.F.R. § 1.116 - EXPEDITED PROCEDURE

Serial Number: 09/477,977

Filing Date: January 5, 2000

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for automatically sealing the flowable material in the implantable device upon removal of the external source,

wherein the implantable device is adapted for implantation within body tissue with the expandable element adjacent a body lumen to provide volume to the body tissue near the lumen for adjustable coaptation of the body lumen.

2. The implantable device according to claim 1, wherein said rear port portion comprises an elastic septum.
3. The implantable device according to claim 1, wherein said elongate conduit has a second elongate passageway extending from an opening in the conduit forward tip end to a location rearward from said expandable element.
4. The implantable device according to claim 1, wherein said expandable element is attached onto said elongate conduit element by a material comprising an adhesive material.
5. The implantable device according to claim 1, wherein said elongated conduit element permits subcutaneous positioning of the rear port portion.
6. The implantable device according to claim 1, wherein the implantable device is constructed using a bio compatible material such as polyurethane or silicone.
7. The implantable device according to claim 1, wherein the rear port portion comprises a compression ring for maintaining a seal of the rear port portion.
8. [AMENDED] An implantable device assembly, comprising:
  - (a) an elongate guide probe member adapted for being inserted into tissue adjacent a body lumen of a patient;
  - (b) an elongate implantable device adapted for being surgically implanted into the

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tissue adjacent to the body lumen, said implantable device including a forward expandable element and a rear port portion connected together by flexible conduit, said conduit having a first inner passageway in fluid communication between said expandable element and said rear port portion and having a second passageway adapted for receiving said elongate probe member; and

(c) an external source containing a flowable material and adapted for connection to the rear port portion of said implantable device, whereby a flowable material from said external source can be introduced through the rear port portion and through the first passageway of said implantable device so as to expand the forward expandable element adjacent a body lumen to add volume to tissue about the lumen to at least partially and adjustably restrict the lumen.

9. The implantable device assembly of claim 8, wherein said guide probe member comprises a stiff elongate rod having a pointed forward end.

10. The implantable device assembly of claim 8, wherein said guide probe member comprises a flexible guidewire.

11. The implantable device assembly of claim 8, wherein said implantable device rear port portion contains an elastic septum and said source is a syringe having a forward facing needle whereby said needle may be sealingly inserted in said septum and a flowable material injected from said syringe through the first passageway to expand the forward expandable element.

12. The implantable device assembly of claim 11, wherein said syringe includes an axially movable rear plunger element, whereby the hollow needle is insertable into the elastic septum located in the rear port portion of the implantable device and a flowable material injected by the plunger element through the hollow needle and first passageway to expand the forward expandable element.

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13. [AMENDED] A method for variably restricting a body lumen in a patient, comprising the steps of:

guiding an elongate implantable device into body tissue of a patient to a location adjacent a body lumen to be restricted using an elongate probe member, the elongate implantable device having an expandable element located at its forward end and having a port portion provided at its rearward end, so that the expandable element is positioned adjacent to the body lumen; and

providing a flowable material from a source into the port portion, so as to expand the expandable element to add volume to tissue near the lumen to at least partially restrict the body lumen,

wherein the implantable device is guided over the elongate probe member.

14. The method of claim 13, further comprising the steps of:

removing the elongate probe member from the patient's body;

positioning the port portion of said elongate implantable device inside the patient's body tissue near the surface of the skin, and

closing an opening made in the patient's skin over the port portion.

15. The method of claim 13, wherein the step of providing a flowable material includes injecting one or more of a saline liquid solution, a gel, or a slurry of particles in a fluid carrier.

16. The method of claim 13, wherein the step of providing a flowable material includes injecting a radiopaque material to facilitate fluoroscopic visualization.

17. The method of claim 13, wherein the elongate probe member and implantable device are surgically inserted to a location adjacent the urethra of a patient.

18. The method of claim 13 including placing an implantable device along two opposite sides of the urethra of a patient.

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19. The method of claim 13, wherein the implantable device is guided over the elongate probe member.
20. The method of claim 13, wherein the implantable device and elongate probe member are inserted into the body tissue as a unit.
21. The method of claim 13, wherein the implantable device is positioned using visual guidance.
22. The method of claim 13, wherein the implantable device is positioned using fluoroscopy.
23. The method of claim 13, further comprising:  
increasing restriction of the body lumen by adding flowable material to the implantable device.
24. The method of claim 13, further comprising:  
decreasing restriction of the body lumen by removing flowable material from the implantable device.
25. The method of claim 13, further comprising:  
measuring restriction of the body lumen by infusing fluid through the body lumen past a restricted portion of the body lumen and measuring back pressure.
26. The method of claim 13, wherein providing a flowable material from a source into the port portion comprises:  
injecting the flowable material into a septum of the port portion using a hyperdermic needle.
27. The method of claim 13, further comprising:

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expanding the expandable element prior to withdrawal of the elongated probe member.

28. [AMENDED] A method for variably restricting a body lumen in a patient, comprising:  
guiding an elongate implantable device into body tissue of a patient to a location  
[adjacent] about a body lumen to be restricted using an elongate probe member, the elongate  
implantable device having an expandable element located at its forward end and having a port  
portion provided at its rearward end, so that the expandable element is positioned adjacent to the  
body lumen; and  
providing a flowable material at the rearward end from a source into the port portion, so  
as to expand the expandable element to at least partially restrict the body lumen;  
wherein the implantable device is positioned using fluoroscopy.
29. The method of claim 28, further comprising:  
withdrawing the elongate probe member from the patient's body;  
positioning the port portion of said elongate implantable device inside the patient's body  
tissue near the surface of the skin, and  
closing an opening made in the patient's skin over the port portion.
30. The method of claim 28, wherein the material includes injecting one or more of a saline  
liquid solution, a gel, or a slurry of particles in a fluid carrier.
31. The method of claim 28, wherein providing a flowable material includes injecting a  
radiopaque material to facilitate fluoroscopic visualization.
32. The method of claim 28, wherein the elongate probe member and implantable device are  
surgically inserted to a location adjacent the urethra of a patient.
33. The method of claim 28, including placing an implantable device along two opposite  
sides of the urethra of a patient.